

DEC 19 1997



P.O. Box 509 Edenvale 1610
Republic of South Africa
Telephone : +27 (11) 609-8640
Telefax : +27 (11) 452-3918

-11-

K972946

510 (k) Summary

Trade name: AURELUX 77
Common name: Dental casting alloy
Classification name: Gold based alloys and precious metal alloys for clinical use
Classification number: EJT

Legally marketed device: Jelenko Jel 96
Description of the device: High gold casting alloy
Intended use of the device: Type IV restorations with porcelain veneering

Summary of the technological characteristics

Test methods applied: as in ANSI/ADA 5 and ISO 9693

Comparison of composition:

ALLOY		COMPOSITION (weight%)								
Name		Au	Ag	Pt	Pd	Cu	Fe	Sn	In	Ir
Legal	Jel 96	78	1.2	6	12	4.5	1	x	x	x
New	Aurelux 77	76.6	1.2	9.9	9.3	0.5	0.2	0.6	.1.5	0.2

x is less than 1 %

Comparison of physical and mechanical properties

ALLOY		Melting point range (°C)		Hardness (Vickers 5/30)		Yield strength (MPa)		Elongation (%)		CTE (x10 ⁻⁶ /°C)	Density (g/cm ³)
Name		solid.	liquid	soft	hard	soft	hard	soft	hard		
Legal	Jel 96	1170	1260		255		655		4	14.5	17.2
New	Aurelux 77	1150	1230	200	245	350	650	19	11	14.1	18.5

Discussion

With the exception of a very small copper content the two alloys have almost identical composition and properties. The noble metal content in both alloys is higher than 95 %. Less than 1 % difference in base metal concentration.

Conclusion

The major constituent (Au) and the noble metal content are similar. Even the residuals are the same elements.

The very high noble metal content suggest an effective biocompatibility





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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jerome D. Davis
Managing Director
Aurex Precious Metal Industries (Pty) Ltd.
P.O. Box 509 Edenvale 1610
Republic of South Africa

Re: K972946
Trade Name: Aurelux 77
Regulatory Class: II
Product Code: EJT
Dated: October 6, 1997
Received: October 17, 1997

Dear Mr. Davis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

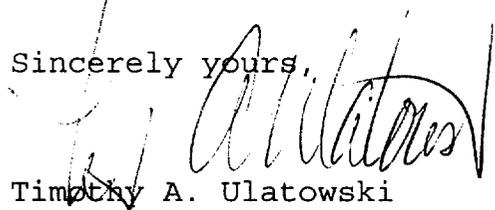
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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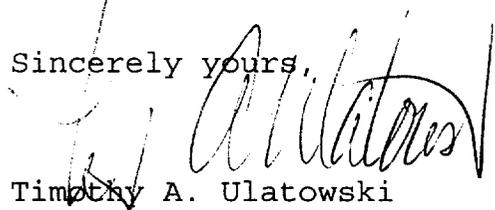
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Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: AURELUX 77

Indications For Use:

Dental casting alloy used in combination with dental ceramics for fabrication of metallo-ceramic restoration.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number KA 2444

Prescription Use _____
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____